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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,745	11/20/2001	Yi Li	1488.0840002	9091

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,745

Applicant(s)

Li

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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- 1) Claims 1 to 20 are pending in the instant application.
- 2) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Correction is required. See M.P.E.P. 2422.03.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 to 7, drawn to an isolated polynucleotide, vector, host cell and methods of use, classified in class 435, subclass 69.1.
 - II. Claims 8 and 9, drawn to an isolated polypeptide, classified in class 530, subclass 350.
 - III. Claim 10, drawn to an antibody, classified in class 530, subclass 388.22.
 - IV. Claims 11 and 13, drawn to an agonistic compound of unspecified constitution and a method of use, classification undeterminable.
 - V. Claims 12 and 14, drawn to an antagonistic compound of unspecified constitution and method of use, classification undeterminable.
 - VI. Claim 15, drawn to a method of gene therapy by administering a DNA encoding an agonistic peptide, classified in class 514, subclass 44.
 - VII. Claim 16, drawn to a method of gene therapy by administering a DNA encoding an antagonistic peptide, classified in class 514, subclass 44.
 - VIII. Claims 17 and 18, drawn to a binding assay, classified in class 436, subclass 501.

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IX. Claim 19, drawn to a method of genetic analysis, classified in class 435, subclass 6.

X. Claim 20, drawn to an immunoassay, classified in class 436, subclass 501.

The inventions are distinct, each from the other because:

The nucleic acid that is invention I, the protein that is invention II, the antibody that is invention III, the agonist of unspecified constitution that is invention IV, the antagonist of unspecified constitution that is invention V, the nucleic acid encoding a receptor agonist which is employed in the gene therapy process of invention VI, and the nucleic acid encoding a receptor antagonist which is employed in the gene therapy process of invention VII are seven structurally and functionally different chemical compounds each of which can be made and used without any one or more of the other compounds. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature or combination of features lacking from the prior art and which has been identified as the basis for that common utility.

In the instant case the product as claimed could be used to detect the presence of the protein of invention II in a sample, which is a process that is materially different from a method of treatment.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The nucleic acid that is invention I can be used in a method of producing the

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protein encoded thereby, which is a method that is materially different from the diagnostic method that is invention IX.

Inventions I and VIII are also related as product and process of use. In the instant case the assay of invention VIII can be practiced with a cell that naturally produces the receptor protein recited therein, which is not encompassed by any of the instant claims.

Inventions III and X are also related as product and process of use. The inventions are distinct because the antibody of invention III can be employed to purify its respective antigen from a mixture of compounds, which method is materially different from the immunoassay of invention XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800